IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

BASF AGRO B.V., MERIAL LIMITED, and MERIAL SAS,	*	
Plaintiffs,	*	
vs.	*	
CIPLA LIMITED, *et al.*,	*	CASE NO. 3:07-CV-125 (CDL)
Defendants,	*	
VELCERA, INC. and FIDOPHARM, INC.,	*	
Intervenors.	*	

O R D E R

Plaintiffs Merial Limited and Merial SAS ("Merial") contend that Velcera, Inc. and FidoPharm, Inc.'s ("Velcera") intended launch of a new product violates this Court's June 21, 2011 Injunction. Merial seeks to have the Court hold Velcera in contempt and enjoin the sale of the new product. Based on the evidence presented at the hearing on May 21-23, 2012, the Court finds that Merial has not carried its burden of proving by clear and convincing evidence that the sale of the new product violates the Court's June 21, 2011 Injunction, and therefore,

Merial's motions for contempt and injunctive relief (ECF Nos. 176 & 177) are denied.[1]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. Standard for Contempt

Merial has the substantial burden of showing by clear and convincing evidence that Velcera has violated the Court's June 21, 2011 Injunction. *See TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 883 (Fed. Cir. 2011); *Riccard v. Prudential Ins. Co.*, 307 F.3d 1277, 1296 (11th Cir. 2002). To carry that burden, Merial must present sufficient evidence to persuade the factfinder "that the truth of [the] factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984) (quoting C. McCormick, Law of Evidence § 320, p. 679 (1954)). The Court, as the factfinder, must determine whether Merial has established that it is highly probable that Velcera's sale of its new product will violate the Court's injunction.

[1] Merial's motion for injunctive relief (ECF No. 176) seeks a *temporary restraining order*. Prior to the hearing on the motion, the Court notified the parties that it was contemplating treating the hearing on the contempt issues as a hearing on the merits for any type of injunctive relief, whether it be preliminary or permanent in nature. Now that the hearing has been completed, the Court finds that the record has been sufficiently developed, and therefore, it treats the hearing held on May 21-23, 2012 as a trial on the merits for any injunctive relief regarding Merial's current contempt allegations. As explained in the remainder of this Order, that relief is denied.

II. The June 21, 2011 Injunction

The June 21, 2011 Injunction, which Merial claims Velcera intends to violate with the imminent launch of a veterinary product, enjoined Velcera from:

> selling, causing to be sold, offering for sale, and causing to be offered for sale in the United States veterinary products for which Cipla participated in the development, manufacture, and/or packaging, which products contain fipronil and methoprene, regardless of brand name, including but not limited to the veterinary products Protektor Plus, PetArmor Plus, TrustGard Plus, and Velcera Fipronil Plus.

Merial Ltd. v. Cipla Ltd., No. 3:07-CV-125 (CDL), 2011 WL 2489753, at *17 (M.D. Ga. June 21, 2011).[2]

The parties have spent substantial effort parsing the Court's June 21, 2011 Order. The Court finds its meaning to be clear. It prevents Velcera from selling (1) a veterinary product in the United States that (2) contains fipronil and methoprene if (3) Cipla participated in the development, manufacture and/or packaging of the product. It is undisputed that Velcera's new product will be sold in the United States and

[2] This injunction arose from the Court's finding that Velcera had acted in concert with Cipla Limited ("Cipla") to violate a previous injunction of the Court, which prohibited Cipla and anyone acting in concert with it from infringing Merial's patent for veterinary flea and tick treatment products containing the active ingredients fipronil and methoprene ("the '329 Patent"). Although the mandate has not yet been returned from the Federal Circuit Court of Appeals, the Court is aware that the Federal Circuit has recently affirmed the Court's previous finding of contempt against Velcera. *See generally Merial Ltd. v. Cipla Ltd.*, Nos. 2011-1471, 2011-1472, 2012 WL 1948879 (Fed. Cir. May 31, 2012).

that it contains the active ingredients fipronil and methoprene. The disputed issue is whether Cipla participated in the development, manufacture or packaging of the product.

III. Cipla's Participation

Velcera intends to sell two new veterinary products in the United States which have been approved by the U.S. Environmental Protection Agency ("EPA") and have product registration names LC-2010-3 Fipronil & S-Methoprene for Cats and LC-2010-4 Fipronil & S-Methoprene for Dogs. For purposes of today's Order, these products will be referred to collectively as the "New PetArmor Plus." No evidence was presented that Cipla has been, or will be, involved in the manufacture, packaging or sale of the New PetArmor Plus. Instead, Merial contends that Velcera's sale of the New PetArmor Plus will violate the June 21, 2011 Injunction because Cipla "participated in the development" of the new product. To prevail, Merial must prove this contention by clear and convincing evidence.

"Participated in the development," as that phrase is used in the Court's June 21, 2011 Injunction, is not a phrase of art. Its plain meaning is easily discernible. To participate in the development of the product means that Cipla must have been involved in a material way in the creation of the product that Velcera now intends to sell. "Material" means that Cipla's involvement must have been significant, substantial, and/or

essential. Merriam-Webster's Online Dictionary, www.merriam-webster.com/dictionary/material (last visited June 4, 2012) (defining material as "having real importance or great consequences").

Merial produced no persuasive evidence (and does not seriously contend) that Velcera colluded with Cipla to develop the New PetArmor Plus. The evidence presented at the hearing demonstrated that the New PetArmor Plus was developed after the Court enjoined the sale of the old product in its June 21, 2011 Order, and no evidence was presented that Velcera had any involvement with Cipla in developing any products after that date. The evidence does establish (and is largely undisputed) that Cipla was actively involved in developing the "Old PetArmor Plus" that the Court enjoined in its June 21, 2011 Order, and that the Old PetArmor Plus is similar to the New PetArmor Plus. Based on this development activity and the close similarities in the two products, Merial argues that the Court should find that Cipla participated in the development of the New PetArmor Plus. Merial asserts two theories in support of this argument. First, it suggests that Cipla, through its development of the old product, provided the "building blocks" upon which the new product was developed, and thus, it should be deemed to have participated in the development of the new product. Second, Merial maintains that Velcera merely "tweaked" the old Cipla-

developed product, which Merial argues is essentially the same as the New PetArmor Plus; and therefore, the Court should conclude that Cipla participated in the development of the New PetArmor Plus. The Court addresses each theory in turn.

A. The "Building Blocks" Theory

Velcera clearly used some of what it learned during its relationship with Cipla prior to the issuance of the June 21, 2011 Injunction to develop the New PetArmor Plus after the issuance of the injunction. While the previous relationship with Cipla certainly established a foundation on which the new product was created, the Court must narrowly construe its injunction to reach only conduct that clearly violates it. Drawing arbitrary lines as to how many building blocks are sufficient to constitute "development" of the new product runs afoul of the fundamental principle that before a person can be held in contempt, the line that the person cannot cross must be clear and the person must have clearly crossed the line. The Court does not find that Velcera should be held in contempt because the old Cipla-developed product provided part of the foundation for the New PetArmor Plus. However, if the two products are essentially the same products, such circumstantial evidence would be a persuasive indicator that Cipla participated in the development of the new product.

B. The "Tweak" Theory

Merial argues that Velcera merely "tweaked" the old Cipla-developed product in its development of the New PetArmor Plus, and that the Court should find that the two products are essentially the same. The New PetArmor Plus is not identical to the Old PetArmor Plus. Although they have the same exact active ingredient formulations, the inert ingredient formulation is different. The old product consists of the following: (1) Fipronil (9.8%), (2) S-Methoprene (11.8%), (3) Ethanol (5%), (4) Butylhydroxyanisole (0.02%), (5) Butylhydroxytoluene (0.01%), (6) NIKKOL HCO-60 (5%), (7) PEG 1000 (5%), and (8) Transcutol P (62.56%). *See e.g.*, Pl.'s Tr. Ex. 302 at VEL009372, Confidential Statement of Formula (submitting Confidential Statement of Formula for Old PetArmor Plus product for cats in support of EPA Minor Formulation Amendment application).[3] The New PetArmor Plus eliminated two of the inert ingredients, NIKKOL HCO-60 and PEG 1000, and replaced the volume from these two ingredients with a corresponding increase in Transcutol P,

[3] The Court notes that the Confidential Statement of Formula lists alternative names for several ingredients in the formulation, but the Court will refer to the names of the ingredients as they are referenced above. Further, it is undisputed that the correct name for the ingredient denominated PEG 100 in the Confidential Statement of Formula is actually PEG 1000. The Court compares the changes made in the PetArmor Plus product for cats, but notes that its analysis similarly applies to the changes made to PetArmor Plus for dogs.

which was included in a lesser concentration in the old product. The new product has the following composition: (1) Fipronil (9.8%), (2) S-Methoprene (11.8%), (3) Ethanol (5%), (4) Butyhydroxyanisole (0.02%), (5) Butylated hydroxyltoluene (0.01%), and (6) Transcutol P (72.56%). *See e.g.*, Pl.'s Tr. Ex. 302 at VEL009373-74, Confidential Statement of Formula (submitting Confidential Statement of Formula for New PetArmor Plus product for cats in support of EPA Minor Formulation Amendment application).

Merial argues that the elimination of the two inert ingredients and a corresponding increase in another inert ingredient was an insignificant change that did not make the new product materially different from the old product. In support of this argument, Merial points to evidence that the manufacturer for the new product was well aware of the old Cipla formula and used it as a standard or control in developing the new formula. Merial also points to Velcera's own EPA registration filings to support its contention that the formula change was insignificant. Specifically, Merial notes that to obtain accelerated regulatory approval, Velcera represented to the EPA that its new product was "identical or substantially similar to" the old product, and that it also convinced the EPA in its application for a Minor Formulation Amendment that the change in the inert ingredients was inconsequential.

Velcera responds that it is unreliable to base an evaluation of the similarities of two chemically formulated products on generalized labels attached to the products during the EPA regulatory process. Instead, Velcera argues that such an evaluation requires rigorous scientific analysis. In support of that position, Velcera presented the testimony of Dr. Wesley Shoop. Based on the evidence presented at the hearing, the Court found Dr. Shoop well qualified in the areas of parasitology and veterinary pesticidal applications and formulations. Dr. Shoop received a bachelor's degree in biology and zoology from the University of Nebraska, a master's degree from Louisiana State University, and a doctorate degree in parasitology from Louisiana State University. Intervenor's Tr. Ex. 198 at 1, Curriculum Vitae for Dr. Wesley L. Shoop. He worked as an assistant professor at Murray State University for two years and also served as an adjunct professor at Rutgers University for ten years. *Id.* Employed by Merck Research Laboratories as a parasitologist for almost twenty years, Dr. Shoop's service included working as Director of Parasitology and as a Distinguished Senior Scientist. *Id.* After leaving Merck, Dr. Shoop worked for DuPont Stine-Haskell Laboratories until 2012, and he is currently the Chief Executive Officer for Delaware Parasitology. *Id.* During his employment with Merck and DuPont, Dr. Shoop formulated spot on applications and pour

on applications for molecules he discovered. He has authored approximately one hundred publications in peer-reviewed journals in the area of parasitology, *id.* at 2-10, and he is credited as an inventor on five U.S. Patents in the area, *id.* at 16. Merial did not object to Dr. Shoop's qualifications or testimony as an expert in the field of veterinary pesticidal applications and formulations.[4]

According to Dr. Shoop's testimony, which was not discredited through other contrary expert testimony, the two inert ingredients that were eliminated have significant crystallization inhibiting characteristics. The two inert ingredients allow the active ingredients to remain dissolved without crystallization for an extended period so that the product remains effective for thirty days, thus allowing for applications of the product every thirty days. By eliminating those crystallization inhibitors and replacing their volume with

[4] Merial did file a Motion in Limine to Strike Expert Reports and Exclude Evidence and Testimony Related to the Validity of the '329 Patent (ECF Nos. 214 & 215), including Dr. Shoop's testimony and expert report. The Court allowed Dr. Shoop to testify at the hearing on the issue of the differences in the formulations of the PetArmor Plus products, and did not consider any testimony by Dr. Shoop relating to the validity of the '329 Patent or whether the New PetArmor Plus product infringed the '329 Patent, as the Court ruled validity of the '329 Patent and infringement were not issues to be decided in this contempt action. Merial's motions (ECF Nos. 213 & 214) are therefore terminated as moot.

an increase in Transcutol P, the formula would have a different delivery mechanism.

Merial's response to this testimony is two-fold. First, Merial suggests that because Velcera previously described the two eliminated inert ingredients as solvents and not "crystallization inhibitors" in its EPA regulatory filings, then it should not now be allowed to describe them as crystallization inhibitors. Dr. Shoop, however, provided a rational explanation that crystallization inhibitors, such as those in the old product, can also be solvents. In other words, they have both characteristics. They help dissolve the active ingredients, while also allowing them to remain dissolved for a longer period of time, due to their crystallization inhibiting qualities. The Court found credible this reconciliation of the perceived contradiction between listing the inert ingredients as solvents and the current position that they are crystallization inhibitors. Second, Merial maintains that if the elimination of these two inert ingredients makes the New PetArmor Plus as different from the old product as suggested by Dr. Shoop, then Velcera made misrepresentations to the EPA when it sought approval of the new product as substantially similar to the previously approved product with a minor formula amendment. The Court does have concerns about the accuracy of some of the representations made to the EPA in light of Dr. Shoop's

testimony. But the Court does not find it appropriate to ignore that expert testimony just because it may be somewhat inconsistent with the representations Velcera made to the EPA, particularly given the fact that the standard for EPA regulatory approval is not the same as what the Court must decide regarding contempt.

In addition to the difference in the formulations of the two products, evidence was presented that the manufacturing processes for the two products are different due to the elimination of two of the inert ingredients. Without those crystallization inhibitors, Velcera concluded that it no longer needs to use heat in the manufacturing process. Dr. Shoop testified that the elimination of that step constitutes a significant difference in the two manufacturing processes. Merial responds that such a conclusion is inconsistent with Velcera's representations to the EPA during the approval process when it represented to the EPA that the manufacturing process for the New PetArmor Plus was substantially the same as the process for the old product. Thus, we have yet another conflict in the evidence.

Weighing all of the evidence as the factfinder, the Court is conflicted. On the one hand, it appears that Velcera considered its New PetArmor Plus to be very close to the old product, and it made representations to that effect to the EPA

because it was in Velcera's best interest to do so to get the new product approved. On the other hand, the Court found the scientific testimony from Velcera's parasitology formulation expert to be persuasive as to the differences in the chemistry between the old and the new formula.[5] The difficulty the Court has had attempting to reconcile these seemingly conflicting positions leads the Court to the inescapable conclusion that the evidence is not clear and convincing that the two products are substantially the same with no material differences. And if the Court cannot find, under the applicable legal standard, that the two products have no material differences, then the Court cannot infer that Cipla participated in the development of the new product.[6]

CONCLUSION

Although *today's* Order does not prohibit Velcera from proceeding with the launch of its new product, the Court

[5] The Court hastens to add that part of the reason the testimony was persuasive is that it was essentially uncontested scientifically, and the Court must make its factual findings based upon the current record. Although the Court also found Merial's EPA regulatory expert credible, he acknowledged that his expertise did not include formulation. The Court expresses no opinion as to whether Dr. Shoop's testimony would retain its persuasive value in a future patent infringement action when compared to comparable expert scientific testimony.

[6] The Court emphasizes that just as it cannot find from the present record that the old and new products are materially the same as a factual matter, it also is not finding that the two products are materially different. The Court simply concludes that in light of the conflicting evidence in the present record, Merial has not carried its heavy burden of proof to support a finding of contempt.

observes Merial is not left without a remedy. Merial has the full opportunity to protect its intellectual property, the '329 Patent, by filing an infringement action against Velcera if it believes the new product violates its patent. And quite frankly, from this Court's perspective, that is the preferred mechanism for resolving the important issue that is at the bottom of this controversy. While this Court would not hesitate to make a finding of contempt if it concluded that its Order had been clearly violated, the exercise of that awesome contempt power should be used sparingly, and only in those cases where the evidence establishes clearly contumacious conduct. This is not such a case based upon the present record. Merial's motions are denied (ECF No. 176 & 177).[7]

IT IS SO ORDERED, this 5th day of June, 2012.

S/Clay D. Land
CLAY D. LAND
UNITED STATES DISTRICT JUDGE

[7] The Court expresses no opinion as to whether Merial would prevail in a patent infringement action. However, the Court does note that today's ruling should have no preclusive effect on any such action given that the issue the Court decides today is not the same issue that would be decided in a patent infringement action and given the fact that Merial was prevented by the Court's rulings from putting up evidence of patent infringement.